

To: Illinois Health Information Exchange Authority Data Security & Privacy Committee

From: Illinois Health Information Exchange Authority; Office of Health Information Technology

Date: October 24, 2013

RE: Implementing House Bill 1017 (PA 98-378) – Patient Choice in Data Sharing, the Illinois Mental Health and Development Disabilities and Confidentiality Act Amendment

Background

On September 19, 2012 the Illinois Health Information Exchange (“ILHIE”) Authority (“Authority”) unanimously endorsed the ILHIE Data Security & Privacy Committee’s (“Committee”) *Report of Preliminary Findings and Recommendations* (“Report”) and subsequently directed the ILHIE Authority to implement the recommendations set forth in the Report.¹

A key recommendation in the Report directed the ILHIE Authority to adopt an Opt-Out approach to patient choice in data sharing through a health information exchange (“HIE”).² The Report examined several statutory barriers pertaining to patient consent requirements for health information sharing that would hinder the widespread adoption of HIE in Illinois. In its Report, the Committee recommended that the ILHIE Authority adopt a Break the Glass policy and act to clarify applicable Illinois law, whether through adoption of appropriate regulations or by seeking to amend State statutes.³ Additionally, the Report directed the ILHIE Authority to adopt measures to build provider and patient trust in the ILHIE, including but not limited to: HIE monitoring, breach mitigation and public education.⁴

After adoption of the Report, the Illinois Office of Health Information Technology (“OHIT”) in collaboration with 10 endorsing entities spearheaded an effort to modernize the Illinois Mental Health and Development Disabilities and Confidentiality Act (“MHDDCA”) to address patient consent requirements and support the State in implementing new health care delivery models.

House Bill 1017

On August 16, 2013 Governor Quinn signed House Bill 1017 into law (PA 098-0378).⁵ Public Act 098-0378 amends the MHDDCA to allow for the exchange of mental health data through a HIE, among other changes. Specifically, the MHDDCA amendment recognizes the role and responsibilities of the ILHIE Authority to facilitate secure electronic health information exchange and modernizes patient mental health data consent requirements in Illinois. The MHDDCA, as amended:

¹ Resolution 2012-11 Regarding Implementation of Privacy and Security Policies available at: http://www2.illinois.gov/gov/HIE/Documents/Resolution2012_11FINAL.pdf.

² ILHIE DSPC Report of Preliminary Findings and Recommendations, #11-15 available at: http://www2.illinois.gov/gov/HIE/Documents/ILHIE_DSPC_Findings_091912_FINAL.pdf.

³ ILHIE DSPC Report of Preliminary Findings and Recommendations, #16-17 available at: http://www2.illinois.gov/gov/HIE/Documents/ILHIE_DSPC_Findings_091912_FINAL.pdf.

⁴ ILHIE DSPC Report of Preliminary Findings and Recommendations, #23 available at: http://www2.illinois.gov/gov/HIE/Documents/ILHIE_DSPC_Findings_091912_FINAL.pdf.

⁵ PA 098-0378 available at: <http://www.ilga.gov/legislation/publicacts/fulltext.asp?Name=098-0378&GA=98>.

- Establishes the patient Opt-Out choice to share mental health data electronically and in real time via an HIE (§9.6)
- Establishes meaningful disclosure requirements and the manner that information will be shared with patients regarding their right to Opt-Out (§9.6)
- Requires the ILHIE Authority's annual review of the feasibility of adopting new technologies that allow for greater patient choice (§9.6)
- Permits disclosure of patient information for care coordination purposes and allows disclosures by and among integrated health systems and members of interdisciplinary teams for treatment purposes without patient consent (§9.0 and §9.2)

The MHDDCA amendment delegates to the ILHIE Authority the responsibility for implementing patient Opt-Out processes, meaningful disclosure and annual review of data segmentation technology. Specifically, the MHDDCA, as amended, directs the ILHIE Authority, "through appropriate rules, standards, or contractual obligations to ... give consideration to the format and content of the meaningful disclosure and the availability to recipients of information regarding an HIE and the rights of recipients ... [and] give annual consideration to enable a recipient to expressly decline the further disclosure by an HIE to third parties of selected portions of the recipient's record while permitting disclosure of the recipient's remaining patient health information".⁶

Patient Consent Implementation Framework

Establishing the ILHIE Authority to govern the operations of the ILHIE demonstrates the State's core commitment "to ensure that the appropriate security and privacy protections apply to health information" in accordance with the ILHIE's enabling legislation.⁷ The ILHIE Authority's actions in establishing the Committee and providing it with the authority to "review, evaluate and recommend ILHIE data privacy and security policies ... with appropriate collaboration with State of Illinois stakeholders, policy developers and implementers" further demonstrate the State and the ILHIE Authority's commitment.⁸

On June 26, 2013 the ILHIE Authority convened the Illinois Patient Consent Management Workshop ("Workshop"). The Workshop began the process by which the ILHIE Authority considers the development of the privacy, security and consent policies to govern the exchange of patient data utilizing HIE in Illinois. The Workshop considered policies for which the ILHIE Authority is responsible pursuant to the MHDDCA amendment as well as breach notification.

The goal of Workshop process is to enable the electronic exchange of patient health information in a secure environment that protects patient privacy and confidentiality by ensuring:

- Patients and health care stakeholders have a clear understanding of how the ILHIE consent process works
- The ILHIE Authority administers and implements consent seamlessly
- HIEs are a widely used tool of health care

⁶ PA 098-0378 available at: <http://www.ilga.gov/legislation/publicacts/fulltext.asp?Name=098-0378&GA=98>.

⁷ PA 096-1331 available at:

<http://ilga.gov/legislation/ilcs/ilcs3.asp?ActID=3267&ChapAct=20%20A0ILCS%203860/&ChapterID=5&ChapterName=EXECUTIVE%20BRANCH&ActName=Illinois%20Health%20Information%20Exchange%20and%20Technology%20Act>.

⁸ Resolution 2012-11 Regarding Creating the ILHIE Data Security & Privacy Committee available at: http://www2.illinois.gov/gov/HIE/Documents/Authority%20Docs/Resolution2011_12FINAL.pdf

The ILHIE Authority invited stakeholder organizations and all interested parties, including but not limited to representatives of patients, providers, health plan payors, government agencies, and regional health information exchanges, as well as attorneys, subject matter experts, consultants, and members of the public, to participate in three privacy and security Work Groups holding inaugural meetings during the Workshop. These Work Groups were convened to solicit stakeholder input and provide recommendations to this Committee for its deliberation.

Patient Consent and Privacy Work Groups

The three Work Groups assembled are as follows: the Patient Choice and Meaningful Disclosure Work Group, the Patient Consent Preferences and Data Security Work Group and the Breach Response Protocol Work Group. Additionally, the Patient Choice and Meaningful Disclosure Work Group formed four Subgroups to better manage its workload: Meaningful Disclosure at the Point of Care, Meaningful Disclosure at the HIE Website, Specially Protected Health Information, and Break the Glass.

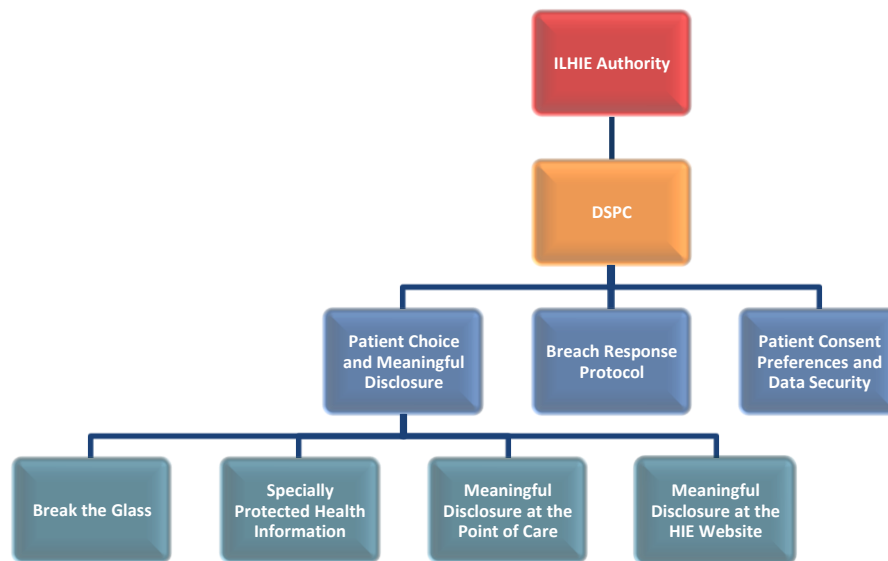


Figure 1: Work Group and Subgroup Structure

Generally, each Work Group was tasked with the following:

Patient Choice and Meaningful Disclosure Work Group: Define the scope and consent of patient Opt-Out consent and meaningful disclosure. Identify and recommend a set of appropriate rules, standards or contractual provisions for the ILHIE to meet the statutory requirements of the MHDDCA amendment. Identify and recommend issues and topics that should be addressed by health care providers at the point of care and develop resources for use by providers. Provide recommendations to the Committee in Fall/Winter 2013.

Patient Consent Preferences and Data Security Work Group: Identify specific patient privacy and security concerns. Evaluate currently available technical solutions to effectively achieve electronic medical record data segmentation. Report on the feasibility of implementing those technologies to meet the statutory requirements of the MHDDCA amendment. Provide recommendations to the Committee in July 2014.

Breach Response Protocol Work Group: Consider and recommend a standard for breach investigation and mitigation obligations arising from the use of the ILHIE between the ILHIE

Authority and ILHIE participants. Recommend a breach response policy to be incorporated into ILHIE participant data sharing agreements. Provide recommendations to the Committee in Fall/Winter 2013.

Each Work Group received detailed objectives, deliverables and action plans.⁹ Work Groups were tasked with creating some or all of the following deliverables:

- HIE policies and procedures establishing best practices for patient Opt-Out consent management;
- Template patient Opt-Out and Opt-In forms for use by providers at the point of care;
- HIE policies and procedures establishing best practices for meaningful disclosure to patients;
- Template language for notice or other deliverables to be given to patients at the point of concerning Opt-Out consent and meaningful disclosure, such as a potential acknowledgement of receipt of meaningful disclosure, brochures or other written notice of a patient's right to opt out of an HIE;
- Recommendations for HIE website content and audio, visual and written instructions regarding how to opt out of participation in an HIE;
- Recommendations about breaking the glass for a patient who opted out from HIE participation in an emergency situation; and
- Standardizing breach investigation, notification and mitigation obligations for the ILHIE and its participants and recommending a Final Breach Response Policy.

Work Group Deliberations

The Work Groups and Subgroups met regularly since the Patient Consent Management Workshop, some meeting as frequently as weekly for multiple hour sessions. Recommended for adoption by the Committee and the ILHIE Authority by the Work Groups and associated Subgroups are policies, procedures, recommendations, notices, and forms. Collectively, these "Recommendations" are attached as Attachments A-H.

Multiple stakeholders contributed to the creation of the Recommendations. In preparing the Recommendations, ILHIE and OHIT staff aimed to accommodate multiple interests, while maintaining primary focus on the patient and the sustainability of the IHLIE.

The ILHIE Authority policies strive to achieve a balance in assuring that individuals' health information is properly protected while allowing the flow of health information needed to provide and promote high-quality health care. Although the Recommendations reflect the input of the Work Groups and the corresponding ILHIE technical functionality, there are aspects of the Recommendations that raised concerns for Work Group participants. Generally, these concerns could be grouped into two categories: patient rights and ILHIE participant responsibilities. Among the more contested issues were:

- Age of consent to share data through the ILHIE
- Level of detail included in meaningful disclosure
- Frequency of meaningful disclosure
- ILHIE user-level management of patient preferences

⁹ Attachment J

The ILHIE Authority acknowledges that the implementation of patient choice in HIE imposes new administrative burdens on ILHIE users, directly or indirectly, as well as corresponding operational responsibilities on the ILHIE. The ILHIE Authority seeks to minimize administrative burdens at the point of care while enabling patients to exercise their rights in protecting their confidentiality and control over their health information.

Work Group member input has been documented extensively in meeting minutes. Work Group meeting minutes are posted and available on the ILHIE website:

<http://www2.illinois.gov/gov/HIE/Pages/PatientConsentManagementWorkshop.aspx>.

Additionally, the Recommendations have been submitted to each Work Group and posted for formal public comment. The public comment period is open until Monday, October 28, 2013 at 5:00pm. Comments received will be posted to the ILHIE website (above). The comments will be provided to the Committee at the Wednesday, October 30, 2013 meeting.

Work Group Recommendations

The Work Groups recommend that the Committee and the Board adopt these Recommendations. The Recommendations are attached for the Committee's review:

- ILHIE Notice (Meaningful Disclosure), Attachment A
- ILHIE Signage (Meaningful Disclosure), Attachment B
- ILHIE Website Content (Meaningful Disclosure), Attachment C
- ILHIE's EHR Connect Opt-Out Form, Attachment D
- ILHIE's EHR Connect Opt-In Form, Attachment E
- ILHIE Authority's Patient Opt-Out Choice and Meaningful Disclosure Policy and Procedure, Attachment F
- Break the Glass recommendation, Attachment G
- Breach Response Policy, Attachment H

Also attached are the following background materials:

- MHDDCA Amendment/PA 098-0378, Attachment I
- Work Group Project Charter and Action Plans, Attachment J
- Work Group Participant List, Attachment K
- ILHIE Data Security & Privacy Committee Report, Attachment L

Schedule and Public Comment

Work Group and Subgroup Chairs and Co-Chairs will present the recommendations to the Committee the October 30 and 31, 2013 meetings. Work Group participants and members of the public will be invited to give public comment in response to these proposed recommendations during the October meetings.

Acknowledgments

OHIT and the ILHIE Authority would like to sincerely thank all of the Work Group participants for their thoughtful consideration and significant time commitment to the development of these Recommendations. OHIT and the ILHIE Authority specifically thank the Chairs and Co-Chairs of each of Work Group for their insights and commitment.

Respectfully submitted,

Illinois Health Information Exchange Authority
Office of Health Information Technology

cc: Patient Consent Executive Steering Committee
Patient Consent Management Work Groups